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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,098	03/22/2000	MASAYUKI TSUCHIYA	053466/0274	7563

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/509,098

Applicant(s)

TSUCHIYA, MASAYUKI

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5, 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 10/29/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/509,098 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 3-5 and 14 are under examination

2. Claims 6-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

4. The following Office Action contains a NEW GROUND of rejection.

5. The request for a CPA filed 10/29/02 requested that the unentered amendment filed 3/18/02 be entered, however, this amendment was entered and a Final rejection was mailed 4/29/02 in response to the amendment. In addition, the request for a CPA did not address the Office action mailed 4/29/02 by an amendment or arguments.

### ***Rejections Withdrawn***

6. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Roguska et al (Protein Engineering 9:895-904, 1996, IDS #3) and further in view of Queen et al (PNAS 86:10029-10033, 1989, IDS #4) is withdrawn in view of the NEW Grounds of rejection below.

***Response to Arguments***

7. The rejection of claim 14 and claims 3-5 under 35 U.S.C. 112, second paragraph, for parts b, g, and h in paragraph 6 of the previous Office Action as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 10/29/02 has been carefully considered but is deemed not to be persuasive because the response did not address this rejection with an amendment or arguments.

8. The rejection of claims 14 and 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 10/29/02 has been carefully considered but is deemed not to be persuasive because the response did not address this rejection with an amendment or arguments.

9. The rejection of claims 3-5 and claim 14 under 35 U.S.C. 103(a) as being unpatentable over Sato et al (Molecular Immunology 31:371-381, 1994, IDS #4) and further in view of Queen et al (PNAS 86:10029-10033, 1989, IDS #4) is maintained.

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The response filed 10/29/02 has been carefully considered but is deemed not to be persuasive because the response did not address this rejection with an amendment or arguments.

10. The rejection of claims 3-5 and claim 14 under 35 U.S.C. 103(a) as being unpatentable over Co et al (PNAS 88:2869-2873, 1991, IDS #4) and further in view of Queen et al (PNAS 86:10029-10033, 1989, IDS #4) is maintained.

The response filed 10/29/02 has been carefully considered but is deemed not to be persuasive because the response did not address this rejection with an amendment or arguments.

***The Following is a NEW GROUND of rejection.***

11. Claims 3-5, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roguska et al (Protein Engineering 9:895-904, 1996, IDS #3) and further in view of Queen et al (PNAS 86:10029-10033, 1989, IDS #4)

The claims recite a method of preparing a humanized antibody comprising obtaining a primary design antibody and conducting a homology search and preparing a list of amino acid sequences with high homology with FR sequences in the primary design antibody and selecting a sequence that matches the amino acid sequences substituted in step 1 and replacing the different amino acids in the FR of the primary antibody with those in the natural FR and expressing and producing the antibody.

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Further claimed is a primary designed antibody comprises CDRs from a rat and the second species is a human.

Roguska et al teach a method of humanization comprising CDR grafting by a homology search between the mouse antibody and human FR regions and selecting the most homologous and then replacing residues in the antibody with those found in the human FR (see page 898, left column, GN901v1.1). Roguska et al do not teach a rat species. This deficiency is made up for in the teachings of Queen et al.

Queen et al teach a method of humanization comprising CDR grafting and homology searching and replacing FR residues and the species mouse and rat (see entire document, especially page 10029, right column, first full paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the a rat antibody for humanization as taught by Queen et al in the methods of Roguska et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the a rat antibody for humanization as taught by Queen et al in the methods of Roguska et al because Queen et al teach that one can use either a mouse or a rat antibody for humanization. Moreover, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have used the a rat antibody for humanization as taught by Queen et al in the methods of Roguska et al because it was routine in the art at the time the claimed invention was made to use mouse as well as rat and other non-human a species as the antibody to humanize. Although Roguska et al does not specifically recite the steps of

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the claimed method in claim 14 it would have been obvious to conduct a homology search using a data base of FR of human antibodies because Roguska et al teach designing based on homology searches of human FR sequences and comparing those residues that are found in the mouse FR with those found at that position in human FR sequences and replacing mouse residues with human to obtain an antibody that are no more likely to be immunogenic than a corresponding CDR-grafted version (see page 901, right column). Thus, it would have been obvious to one of skill in the art to select FR that are more human like in order to reduce the immunogenicity and obviously those FR that are fully human would be less immunogenic in humans.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Conclusion***

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of

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this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.